REGISTRATION 88482-2

AG-CHEM CONSULTING
PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS@AG-CHEM.COM
(703) 266-4377 FAX

September 13, 2011

Shaja Joyner
Product Manager 20
Fungicide Branch
Registration Division (7505P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Oxytetracycline Hydrochloride Technical
Notification of Final Printed Labels
EPA Reg. 88482-2

Dear Mr. Joyner,

Ag-Chem Consulting, on behalf of MGF Scientific Inc., hereby submits the following notification of final printed labels for the above product. Per your request we have enclosed one (1) copy for your review.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for MGF Scientific Inc.

Please read instructions on reverse before comp[illegible] form. Form Approved. OMB No. 2070-0080. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
MGF Scientific Inc./88482-2	Shaja Joyner	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
MGF Scientific Inc./ Oxytetracycline Hydrochloride	20	

5. Name and Address of Applicant *(Include ZIP Code)*

Ag-Chem Consulting
12208 Quinque Lane
Clifton VA 20124

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☑ Notification - Explain below.

☑ Final printed labels in repsonse to Agency letter dated September 1, 2011

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Final Printed Labels.
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40CFR152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections f2 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	55lbs	☑ On Container

6. Manner in Which Label is Affixed to Product: ☑ Lithograph Paper glued Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Matthew Brooks	Regulatory Consultant	703-266-0128

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
[signature]	Regulatory Consultant	Matthew Brooks	9-14-11

Oxytetracycline Hydrochloride Technical

This material is a technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for use or consumption by humans or animals.

Not for Resale under this Label.

Active Ingredient:	
Oxytetracycline hydrochloride*	99.0%
Other Ingredients:	1.0%
	100.00%

*Equivalent to 91.7% oxytetracycline

Net Contents:

EPA Reg. No. 88482-2 **EPA Est No. 1623-NE-001**

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID Call a poison control center or doctor immediately for treatment advice.	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If On Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact the American Association of Poison Control Centers at 1-800-222-1222 for emergency medical treatment information.	

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary, or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its products with the EPA as a pesticide for acceptable use patterns.

Only for formulation into an antibacterial pesticide for the following uses:
Terrestrial Non-Food & Domestic Outdoor

This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U. S. EPA data submission requirements regarding the support of such uses.

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Triple rinse the container to remove any leftover residue from the container. Then offer for recycling if available or dispose of the empty bag in a sanitary landfill or by incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Conditions of Sale and Limitation of Warranty and Liability

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, materials, resistant strains or other influencing factors in the use of the products, which are beyond the control of MGF Scientific, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold MGF Scientific, Inc. and Seller harmless for any claims relating to such factors.

MGF Scientific, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with direction under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or MGF Scientific, Inc. and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MGF SCIENTIFIC, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall MGF Scientific, Inc. or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MGF SCIENTIFIC, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OR WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE election OF MGF SCIENTIFIC, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

MGF Scientific, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of MGF Scientific, Inc.

MGF Scientific, Inc.
P.O. Box 210347
Royal Palm Beach, FL 33421
(561) 798-1377

NOT REVIEWED
in Accordance with PR Notice 82-2
Based on Draft Labeling Dated
9/1/11

Material Sent for Data Extraction

Reg. # 88482-2

Description: _____

☐ Material(s) Sent to Data Extraction Contractors:

- ☐ New Stamped Label Dated _____
- ☒ Notification Dated 1/17/12
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☐ Decision #: 459276

☐ Other Action/Comments: _____

_____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Heather Garvie

Phone: 308-0034 Division: RD

Date: ~~1/18/12~~ 1/19/12

jacto

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

JAN 17 2012

Dr. Matthew Brooks
Director, Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA 20124

Subject:	Application for Pesticide Notification (PRN 98-10)
Submission Date:	12/19/11
Product Name:	Oxytetracycline Hydrochloride Technical
EPA Reg. No.:	88482-2
EPA Decision Number:	459276

Dear Dr. Brooks:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10.

The Agency acknowledges the alternate CSF for this product.

The CSF submitted with the application has been placed in our records. If you have questions concerning this letter, please contact Heather Garvie at 703-308-0034 or me at 703-308-3194.

Sincerely,

Shaja Joyner

Shaja Joyner
Product Manager 20
Fungicide Branch
Registration Division (7505P)

AG-CHEM CONSULTING
PESTICIDE SCIENCE AND REGISTRATION
12208 QUINQUE LANE, CLIFTON VA 20124
(703) 266-0128 MWBROOKS@AG-CHEM.COM
(703) 266-4377 FAX

December 19, 2011

Shaja Joyner
Product Manager 20
Fungicide Branch
Registration Division (7505P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Oxytetracycline Hydrochloride Technical
Notification of Additional Production Site
EPA Reg. 88482-2

Dear Ms. Joyner,

Ag-Chem Consulting, on behalf of MGF Scientific Inc., hereby submits the following notification of an alternate CSF listing an additional repackaging site for this technical product. It has been listed in box 2. No other changes have been made.

Should you have any questions or require additional information, please do not hesitate to contact me at 703-266-0128.

Very Sincerely,

Dr. Matthew Brooks
Director, Ag-Chem Consulting
An Authorized Representative for MGF Scientific Inc.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
MGF Scientific Inc./88482-2

2. EPA Product Manager
Shaja Joyner

3. Proposed Classification
[x] None [ ] Restricted

4. Company/Product (Name)
MGF Scientific Inc./ Oxytetracycline Hydrochloride

PM#
20

5. Name and Address of Applicant *(Include ZIP Code)*

Ag-Chem Consulting
12208 Quinque Lane
Clifton VA 20124

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in ropsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional pages if necessary. (For section I and Section II.)

Notification of Alternate CSF for repackaging site
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40CFR152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Meterial This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yas [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information
[x] Label [ ] Container

4. Size(s) Retail Container
5 lbs

5. Location of Label Directions
[x] On Container

6. Manner in Which Label is Affixed to Product
[x] Lithograph / Paper glued / Stenciled
[ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dr. Matthew Brooks	Regulatory Consultant	703-266-0128

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature

3. Title
Regulatory Consultant

4. Typed Name
Matthew Brooks

5. Date
12-19-2011

Material Sent for Data Extraction

Reg. # 88482-E / 88482-2

Description: New Registration / Label

☐ Material(s) Sent to Data Extraction Contractors:

- ☒ New Stamped Label Dated 9/1/11
- ☐ Notification Dated _____
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

_____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Heather Garvie

Phone: 308-0034 Division: RD

Date: 9/7/11

jacket

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
88482-2	SEP 0 1 2011

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

Term of Issuance:
Conditional

Name of Pesticide Product:
Oxytetracycline Hydrochloride Technical

Name and Address of Registrant (include ZIP Code):

MGF Scientific Inc.
17894 73rd Ct. N
Loxahatchee, FL 33470

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Revise the "EPA Registration Number to read, "EPA Reg. No. 88482-2.

Signature of Approving Official:

Shaja B. Joyner

Shaja B. Joyner, Product Manager (20)
Fungicide Branch, Registration Division (7505P)

Date: SEP 0 1 2011

EPA Form 8570-6

3. Update the heading "Container Disposal" to "Container Handling" in the Storage and Disposal section on page 2.

4. Submit one copy of the revised final printed label for the record before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Shaja B. Joyner
Product Manager (20)
Fungicide Branch
Registration Division (7505P)

Enclosures: Label stamped "Accepted with Comments"; TRB Acute Toxicology review (DP 391363); TRB Product Chemistry review (DP 391074)

Oxytetracycline Hydrochloride Technical

This material is a technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for use or consumption by humans or animals.

Not for Resale under this Label.

Active Ingredient:	
Oxytetracycline hydrochloride*	99.0%
Other Ingredients:	1.0%
	100.00%

*Equivalent to 91.7% oxytetracycline

Net Contents:

EPA Reg. No. 88482-E **EPA Est No.**

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID Call a poison control center or doctor immediately for treatment advice.	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If On Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact the American Association of Poison Control Centers at 1-800-222-1222 for emergency medical treatment information.	

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary, or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its products with the EPA as a pesticide for acceptable use patterns.

Only for formulation into an antibacterial pesticide for the following uses:
Terrestrial Non-Food & Domestic Outdoor

This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U. S. EPA data submission requirements regarding the support of such uses.

ACCEPTED
with COMMENTS
In EPA Letter Dated
SEP 01 2011
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 88482-2

MASTER 8/16/2011

MGF Scientific, Inc.

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse the container to remove any leftover residue from the container. Then offer for recycling if available or dispose of the empty bag in a sanitary landfill or by incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Conditions of Sale and Limitation of Warranty and Liability

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, materials, resistant strains or other influencing factors in the use of the products, which are beyond the control of MGF Scientific, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold MGF Scientific, Inc. and Seller harmless for any claims relating to such factors.

MGF Scientific, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with direction under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or MGF Scientific, Inc. and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MGF SCIENTIFIC, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall MGF Scientific, Inc. or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MGF SCIENTIFIC, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OR WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF MGF SCIENTIFIC, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

MGF Scientific, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of MGF Scientific, Inc.

MGF Scientific, Inc.
P.O. Box 210847
Royal Palm Beach, FL 33421
(561) 798-1377

#88482-E
P.C Code 006308

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETYAND
POLLUTION PREVENTION

Similarity action

July 18, 2011

MEMORANDUM

Subject:	Name of Pesticide Product:	**Oxytetracycline hydrochloride Technical**
	EPA Reg. No. /File Symbol:	88482-E
	DP Barcode:	391363
	Decision No.:	449274
	PC Code:	006308
	Action Code:	R300

From: Masih Hashim, Toxicologist-Team Leader
Technical Review Branch
Registration Division (7505C)

Bryan T. Bunker
7-20-2011

To: Heather Garvie, RM Team 20
Fungicide Branch
Registration Division (7505C)

Registrant: MGF Scientific Inc.
Royal Palm Beach, FL 33421

FORMULATION FROM LABEL:

Active Ingredient(s):		% by wt.
Oxytetracycline hydochloride		99.0
Inert Ingredient(s):		1.0
	Total:	100.0

ACTION REQUESTED: To determine if the cited and the proposed products are similar (74896-5 and 88482-E).

RECOMMENDATIONS: We have examined the formulations of the cited and the proposed products. The are substantially similar in toxicity. The Signal Word for both the products is Danger. TRB has no objection to bridging data between them.

The CSF (dated 5-23-11) for the proposed product should be approved by Product Chemistry/TRB.

This memorandum pertains only to the decision concerning whether the subject product is substantially similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no determinations of the adequacy of the toxicological data base or the precautionary label of the cited product.

FEE

BARCODE: D391074; **Reg. No. /FILE SYMBOL No.:** 88482-E; **PRODUCT:** Oxytetracycline Hydrochloride TGAI/MUP

Date: July 12, 2011

SUBJECT: FEE. Product Chemistry Review of Oxytetracycline Hydrochloride Technical TGAI/MUP

FROM: Shyam Mathur
Product Chemistry Team Leader
Technical Review Branch/RD

S Barnathan 7/12/11

TO: Heather Garvie / Shaja Joyner, RM 20
Fungicide Branch / RD (7505P)

DP BARCODE: D391074
DECISION No.: 449274
Registration Number / File Symbol No.: 88482-E
PRODUCT NAME: Oxytetracycline hydrochlorideTechnical
PCC: 006308
REGISTRANT: MGF Scientific Incorporation
USE: Fungicide
FOOD USE: Yes [ ] No [X]
MRID Numbers: 484851-01 and 484851-02

INTRODUCTION:

The registrant has submitted an application for the registration of the new manufacturing use product oxytetracycline hydrochloride Technical. [redacted] The registrant has submitted group A & group B data for the proposed MUP. The registrant has also submitted a CSF for basic formulation (dated 05-02-11) and the product label. The revised product chemistry data under MRID No. 484851-01 and the revised basic CSF (dated 07-07-11) were submitted on July 7, 2011. The registrant has claimed that the proposed MUP is substantially similar to the registered MUP with Reg. No. 74896-5. TRB has been asked to determine the acceptability of the product chemistry data submitted to support the basic CSF and determine its similarity to the registered product.

SUMMARY OF FINDINGS:

1. The registrant has submitted a proposed revised basic formulation CSF (dated 07-07-11) for oxytetracycline hydrochloride tgai/mup. The average purity of the active ingredient in TGAI/MUP is 99.0%, as determined by the five batch analysis which is also product label claim. The registrant has proposed standard certified limits for the AI. [redacted], the certified limits for which are based on the experimental data obtained from the analytical profile of five batches of oxytetracycline hydrochloride technical/mup. The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320 and 158.350 respectively [MRID No. 484851-01].

Manufacturing process information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

2. The registrant has submitted the specifications for all the starting materials used in the production of oxytetracycline hydrochloride mup/technical. [redacted]. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.325 [MRID No. 484851-01].

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.330. [redacted] The applicant has provided the details of the fermentation process with reaction conditions, equipment used, working up procedures, and quality assurance steps [MRID No. 484851-01].

4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.340. According to the registrant during the production of oxytetracycline hydrochloride tgai/mup, [redacted] in the preliminary analysis [MRID No. 484851-01[.

5. The data submitted corresponding the guidelines 830.1700 (preliminary analysis) & 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.345 and 158.350 respectively. The study was conducted under GLP requirements in compliance with 40CFR§160. The analysis study was performed by Eurofins/Product Safety Labs, Dayton, NJ, USA. Five representative batches of the oxytetracycline hydrochloride tgai/mup were analyzed for percent active ingredient and the impurities present at 0.1% or greater. The samples were analyzed by HPLC and Karl Fisher titration. The registrant has provided details for each of the analytical methods used for the determination of the active ingredient, and the associated impurities. The analytical methods were validated for accuracy, linearity, and precision [MRID Nos. 484851-02].

6. The registrant has submitted data for the guidelines: 830.6302 (color), 830.6303 (physical-state), 830.6304 (odor), 830.6313 (stability to normal & elevated temperature, metal & metal ions), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explodability), 830.6319 (miscibility), 830.6321 (dielectric breakdown voltage), 830.7000 (pH), 830.7050 (UV/VIS), 830.7100 (viscosity), 830.7200 (melting point), 830.7220 (boiling point), 830.7300 (density), 830.7370 (dissociation constant), 830.7550 (Ko/w), 830.7840 (solubility in water and organic solvents), and 830.7950 (vapor pressure) satisfy the data requirements of 830 series group B (physical-chemical properties) [MRID No. 484851-01].

7. The registrant has stated that the oxytetracycline hydrochloride is stable for one year and is not corrosive as demonstrated by one year studies corresponding to guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics).

BARCODE: D391074; **Reg. No. /FILE SYMBOL No.:** 88482-E; **PRODUCT:** Oxytetracycline Hydrochloride TGAI/MUP

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for oxytetracycline hydrochloride TGAI/MUP and has concluded that:

1. All the product chemistry data submitted corresponding to the guidelines 830 Series group A are acceptable.

2. The group B (physical-chemical properties) product chemistry data submitted for the proposed product are acceptable, including one year storage stability (830.6317) and corrosion characteristics (830.6320) studies.

3. The proposed revised CSF for basic formulation (dated 07-07-11) is acceptable.

4. The proposed product with File Symbol No. 88482-E was determined to be substantially similar to the cited product with Reg. No. 74896-5 from the product chemistry point of view. [redacted]

BARCODE: D391074; **Reg. No. /FILE SYMBOL No.:** 88482-E; **PRODUCT:** Oxytetracycline Hydrochloride TGAI/MUP

830.1550: Product identity & composition:

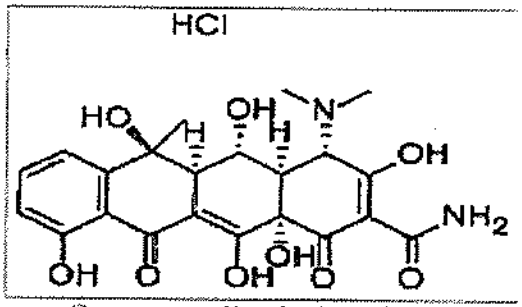
Chemical name: oxytetracycline hydrochloride

CAS No. 2058-46-0

Molecular formula: $C_{22}H_{25}ClN_2O_9$

Molecular weight: 496.89

Structural formula:



Oxytetracycline hydrochloride

BARCODE: D391074; **Reg. No. /FILE SYMBOL No.:** 88482-E; **PRODUCT:** Oxytetracycline Hydrochloride TGAI/MUP

Table 1. Manufacturing and Impurity Data for Oxytetracycline hydrochloride Technical TGAI/MUP

GLN	Requirement	MRtD	Status	Details and /or Deficiency
830.1550	Product identity and composition	484851-0t	A	The NC of AI (99.0%) is supported by a 5 batch analysis and agrees with the label claim nominal concentration. A revised basic CSF (dated 07-06-tt) has been submitted.
830t600	Description of materials used1o produce the product	484851-01	A	The description and composition for all starting materials was provided.
830. t620	Description of production process	48485t-0t	A	The product is produced a fermentation process. The full details of the manufacturing process have been provided.
830.1670	Oiscussion of formation of impurities	484851-01	A	The registrant has reported [redacted] during the five batch analysis of the product. There are no other organic impurities reported in the proposed product.
830.1700	Preliminary analysis	484851-02	A	Five batches of product were analyzed for the a.i. and for the impurities. The results of the five batches support the proposed basic CSF. The analytical method (HPLC-UV) for the determination of the active ingredient was validated for linearity, precision and accuracy.
830.1750	Certified limits	484851-01 CSF (dated 7-6-11)	A	Standard certified limits have been proposed for the AI. As reported in the revised basic CSF.
830.t800	Enforcement analytical method	48485t-0t	A	The HPLC-UV method was used for the determination of the active ingredient. The method has been validated for linearity, precision and accuracy.

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)

Manufacturing process information may be entitled to confidential treatment

BARCODE: D391074; **Reg. No. /FILE SYMBOL No.:** 88482-E; **PRODUCT:** Oxytetracycline Hydrochloride TGAI/MUP

830 Series Subgroup B (Physical-Chemical Properties) Table 2: Physical and Chemical Properties of : Oxytetracycline hydrochloride Technical TGAI/MUP

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	484851-01	A	Yellow
830.6303	Physical state	484851-01	A	Solid (powder)
830.6304	Odor	484851-01	A	Slightly acidic odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	484851-01	A	Known1o be stable to metal & metal ions and elevated temperatures
830.6314	Oxidation/reduction: chemical incompatibility	484851-01	A	Chemically inert
830.6315	Flammability	484851-01	NA	
830.6316	Explodability	484851-01	A	Not explosive
830.6317	Storage stability	484851-01	A	Known to be stable
830.6319	Miscibility	484851-01	N/A	Not intended 1or dilution in organic solvents
830.6320	Corrosion characteristics	484851-01	I	Non-corrosive
830.7000	pH	484851-01	NA	2.4 (1% solution)
830.7050	UV/Visible absorption	484851-01	NA	Molecule does not have any adsorption in UV/Vis range.
830.7100	Viscosity	484851-01	N/A	Product is not a liquid
830.7200	Melting point	484851-01	A	180°C
830.7220	Boiling point	484851-01	N/A	Product is a solid
830.7300	Density	484851-01	A	0.20 g/cc
830.7370	Dissociation constants in water (DC)	484851-01	NA	
830.7550	Partition coefficient	484851-01	A	The test substance is completely soluble in water
830.7840	Water solubility	484851-01	A	Completely soluble in water
830.7950	Vapor pressure	484851-01	A	Negligible and too low to determine using standard methods being salt

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Upgrade (additional information required); W = waiver request

BARCODE: D391074; **Reg. No. /FILE SYMBOL No.:** 88482-E; **PRODUCT:** Oxytetracycline Hydrochloride TGAI/MUP

830.1800. Enforcement analytical method: (MRID No. 484851-01)

Determination of the Concentration of Oxytetracycline Hydrochloride in Technical Formulations

Introduction: Granular Oxytetracycline Hydrochloride is dissolved in acidified water and determined by HPLC.

Materials:
50 mL Volumetric Flask
Aqueous 0.01M HCL Solution
Sonicator
HPLC System (Instruments parameters are provided in table on next page)

Mobile phase:

Tetrabutylammonium hydrogen sulfate solution— Dissolve 1 g of tetrabutylammonium hydrogen sulfate in 100 mL of water. Adjust with 1 N sodium hydroxide to a pH of 7.5.

Edetate disodium solution— Dissolve 0.04 g of edetate disodium in 100 mL of water. Adjust with 1 N sodium hydroxide to a pH of 7.5.

pH 7.5 Phosphate buffer— Prepare a mixture of 0.4 M dibasic potassium phosphate and 0.4 M monobasic sodium phosphate (85:15). Adjust, if necessary, by adding more of the appropriate component to a pH of 7.5.

Diluent : Pipette 20mL of 0.5N HCl to 1000mL volumetric flask. Make up to volume with water. Mix well.

Mobile phase— Transfer, with the aid of 400 mL of water, 100 g of tertiary butyl alcohol to a 2000-mL volumetric flask. Add 120 mL of *pH 7.5 Phosphate buffer*, 100 mL of *Tetrabutylammonium hydrogen sulfate solution*, and 20 mL of *Edetate disodium solution*, and dilute with water to volume. Degas before use. Make adjustments if necessary.

Solution and Sample Preparation:

Preparation of Reference Stock Solutions:
Approximately 25 mg of reference standard was weighed into a 50 mL volumetric flask and diluted to volume with 0.01 M HCl. The solution was sonicated for 3 minutes.

Working Reference Standard Preparation
Appropriate dilutions were made by transferring appropriate amount of stock to 50 mL volumetric flasks and brought to volume with 0.01 M HCl.

Test Sample Preparation
Accurately measure about 25 mg of test substance into a 50 mL volumetric flask and bring to volume with 0.01 M HCL. Sonicate for 3 minutes.

Analysis
At the beginning of the analysis the instrument is equilibrated. The standards and samples were injected at consistent time intervals to maintain a steady baseline. Each set contained a reference standard and solvent blank. All samples are run in duplicate.

% Purity = ((Calculated Concentration (ug/ mL)) / Sample concentration (ug/mL)) x 100

Where:
Calculated Concentration = (Sample Peak area/ Average standard response factor) x Standard Purity

Average Standard Response Factor = Avg [Standard response ratio/ standard conc (ug/mL)]

HPLC Operating Conditions

Column	Phenomenox, Polymer X, 4.6 x 150 mm, 5um
Column Temperature	30°C
Injection Volume	10 ul
Detector	UV Absorbance
Wavelength	254 nm
Flow Rate	1.5 mL/min
Run time	20 min
Retention time	About 9.12 min
Elution	Isocratic

Quality Control
Detector Linearity: Detector response linearity was confirmed using reference standard solutions. Solutions were prepared by performing a series of dilutions from the stock reference standard solution targeting a range from 20 to 80 ug/mL and then diluting to volume with acetonitrile. Linear regression of peaks should give a coefficient of determination (r2) of 0.9996 or better.

Precision: Chromatography of five replicate injections of the midpoint linearity solution should produce a relative standard deviation less than 1.0%.

BARCODE: D391074; **Reg. No. /FILE SYMBOL No.:** 88482-E; **PRODUCT:** Oxytetracycline Hydrochloride TGAI/MUP

CONFIDENTIAL APPENDIX

The following proposed revised Basic CSF (dated 07-06-11) was submitted for oxytetracycline HCl TGAI/MUP:

[redacted]

Revised product chemistry report and CSF for oxytetracycline HCl
Matthew Brooks to: Shyam Mathur 07/07/2011 04:52 PM
Cc: Shaja Joyner

Matthew Brooks	Revised product chemistry report and CSF for oxytetracycline HCl

Hi Shyam
As per our conversation today with Debbie McCall, attached find scans of revised CSF and product chemistry report for oxytetracline hcl technical.
I will submit 3 copies of the report to front end processing.
Thanks for all your help.
-Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

BARCODE: D391074; **Reg. No. /FILE SYMBOL No.:** 88482-E; **PRODUCT**: Oxytetracycline Hydrochloride TGAI/MUP

CONFIDENTIAL APPENDIX

Pages 26-32 – *Manufacturing process information may be entitled to confidential treatment*

Re: oxytetracycline hydrochloride - 88482-E
Matthew Brooks
to:
Heather Garvie
08/11/2011 02:03 PM
Cc:
Michele Lussos
Hide Details
From: Matthew Brooks <mwbrooks01@yahoo.com>

To: Heather Garvie/DC/USEPA/US@EPA

Cc: Michele Lussos <michele@ag-chem.com>

Please respond to Matthew Brooks <mwbrooks01@yahoo.com>

1 Attachment

MGF Manufacturing Use Label-august2011.doc

Hi Heather
See if this is better.
-Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

From: "Garvie.Heather@epamail.epa.gov" <Garvie.Heather@epamail.epa.gov>
To: Matthew Brooks <mwbrooks01@yahoo.com>
Sent: Thursday, August 11, 2011 11:40 AM
Subject: Fw: oxytetracycline hydrochloride - 88482-E

Matt:
So the label you resent me has a name change at the top of the label,

oxytetracycline hydrochloride - 88482-E
Heather Garvie to: Matthew Brooks 08/11/2011 08:49 AM

Hi Matt:

I've got the pchem and acute tox reviews back for the PRIA for 88482-E. I'm looking at the label now and need a few updates to it before passing it on to Shaja for review and signature. The changes/updates are as follows:

1. update "Container Disposal" heading to read "Container Handling". Also, please insert the residue removal instructions. Here is a link to the label review manual. Take a look at the tables toward the end of the chapter for appropriate wording:

http://www.epa.gov/oppfead1/labeling/lrm/chap-13.pdf

If you have any questions, let me know before you resubmit the label so we can get it right the first time.

2. Update your Warranty section. Please see label review manual link as well for appropriate warranty language (starting on page 12-8). You need to state "To the extent consistent with applicable law..." The phrase, "to the extent consistent with applicable law" has been added to the disclaimers of liability and damages to avoid the statements being false or misleading. Some states or localities may not allow certain disclaimers of liability or damages; therefore, the user/buyer may have a remedy under other law governing warranties. Please see examples of Warranty statements in this chapter:

http://www.epa.gov/oppfead1/labeling/lrm/chap-12.pdf

Please make the changes and resubmit to me electronically via email. I will note the resubmission in our our tracking database. Please confirm that you can send me these updates to the label no later than August 19, 2011. The PRIA is 9/5/11 which falls on a holiday, so really it's 9/2/11. I need time to get the package to Shaja for review and signature, so really need a revised label by the 19th if at all possible.

Looking forward to hearing from you. Please confirm you received this email.
Heather

Heather A. Garvie
Registration Division
Office of Chemical Safety and Pollution Prevention (7504P)
U.S.EPA
1200 Pennsylvania Ave. NW
Washington, DC 20460
phone: 703-308-0034
www.epa.gov

Oxytetracycline Hydrochloride Technical

This material is a technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for use or consumption by humans or animals.

Not for Resale under this Label.

Active Ingredient:	
Oxytetracycline hydrochloride*	99.0%
Other Ingredients:	1.0%
	100.00%

*Equivalent to 91.7% oxytetracycline

Net Contents:

EPA Reg. No. **EPA Est No.**

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID Call a poison control center or doctor immediately for treatment advice.	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If On Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact the American Association of Poison Control Centers at 1-800-222-1222 for emergency medical treatment information.	

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary, or human purposes. necessary? ✓ yes' ok

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its products with the EPA as a pesticide for acceptable use patterns.

Only for formulation into an antibacterial pesticide for the following uses:
Terrestrial Non-Food & Domestic Outdoor

This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U. S. EPA data submission requirements regarding the support of such uses.

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Then offer for recycling if available or dispose of the empty container in a sanitary landfill or by incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Conditions of Sale and Limitation of Warranty and Liability

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, materials, resistant strains or other influencing factors in the use of the products, which are beyond the control of MGF Scientific, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold MGF Scientific, Inc. and Seller harmless for any claims relating to such factors.

MGF Scientific, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with direction under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or MGF Scientific, Inc. and Buyer and User assume the risk of any such use. MGF SCIENTIFIC, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

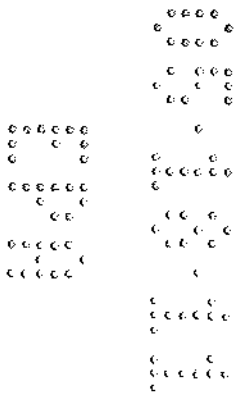
In no event shall MGF Scientific, Inc. or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MGF SCIENTIFIC, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OR WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF MGF SCIENTIFIC, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

MGF Scientific, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of MGF Scientific, Inc.

MGF Scientific, Inc.
P.O. Box 210847
Royal Palm Beach, FL 33421
(561) 798-1377

need to update "To the extent..."

needs residue removal instructions



RG OTC Technical

Comment [hg1]: Name change?

This material is a non-sterile, non-pharmaceutical grade, technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Comment [hg2]: Missing "not for use or consumption....."

Not for Resale Under This Label

Active Ingredient:	
Oxytetracycline hydrochloride*	98.30%
Other Ingredients:	1.70%
	100.00%

*minimum 91.0% oxytetracycline

Comment [hg3]: Different from original label

EPA Reg. No. 88482-E **EPA Est No.**

KEEP OUT OF THE REACH OF CHILDREN
DANGER

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If On Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact InfoTrac at 1-800-535-5053 for emergency medical treatment information.	

See Side Panel for Additional Precautions

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

MGF Scientific
P.O. Box 210847
Royal Palm Beach, FL 33421

NET CONTENTS:

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary, or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing \this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with it labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its products with EPA as a pesticide for acceptable use patterns.

Only for formulation into an anti-bacterial pesticide for the following uses:

Terrestrial Non-Food & Domestic Outdoor

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
Container Handling: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Then offer for recycling if available or dispose of the empty bag in a sanitary landfill or by incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Conditions of Sale an Limitation of Warranty and Liability

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this products. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, materials, resistant strains or other influencing factors in the use of the products, which are beyond the control of MGF Scientific or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold MGF Scientific and Seller harmless for any claims relating to such factors.

MGF Scientific warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with direction under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or MGF Scientific , and Buyer and Use assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MGF SCIENTIFIC MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall MGF Scientific or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXLUSIVE REMEDY OF THE USE OR BUYER, AND THE EXCLUSIVE LIABILITY OF MGF SCIENTIFIC AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OR WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF MGF SCIENTIFIC OR SELLER, THE REPLACEMENT OF THE PRODUCT.

MGF Scientific and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of MGF Scientific.

8/11/11

RG OTC Technical

This material is a non-sterile, non-pharmaceutical grade, technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for Resale Under This Label

Active Ingredient:

Oxytetracycline hydrochloride*	98.30%
Other Ingredients:	1.70%
	100.00%

*minimum 91.0% oxytetracycline

EPA Reg. No. 88482-E **EPA Est No.**

KEEP OUT OF THE REACH OF CHILDREN
DANGER

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If On Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact InfoTrac at 1-800-535-5053 for emergency medical treatment information.	

See Side Panel for Additional Precautions

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

MGF Scientific
P.O. Box 210847
Royal Palm Beach, FL 33421

NET CONTENTS:

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary, or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing \this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with it labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its products with EPA as a pesticide for acceptable use patterns.

Only for formulation into an anti-bacterial pesticide for the following uses:

Terrestrial Non-Food & Domestic Outdoor

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
Container Handling: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Then offer for recycling if available or dispose of the empty bag in a sanitary landfill or by incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Conditions of Sale an Limitation of Warranty and Liability

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this products. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, materials, resistant strains or other influencing factors in the use of the products, which are beyond the control of MGF Scientific or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold MGF Scientific and Seller harmless for any claims relating to such factors.

MGF Scientific warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with direction under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or MGF Scientific , and Buyer and Use assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, MGF SCIENTIFIC MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall MGF Scientific or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXLUSIVE REMEDY OF THE USE OR BUYER, AND THE EXCLUSIVE LIABILITY OF MGF SCIENTIFIC AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OR WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF MGF SCIENTIFIC OR SELLER, THE REPLACEMENT OF THE PRODUCT.

MGF Scientific and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of MGF Scientific.

oxytetracycline hydrochloride submissions - questions please!
Heather Garvie to: Matthew Brooks 06/22/2011 02:05 PM

Hi Matthew:

I've been assigned to two oxytetracycline hydrochloride actions - 88482-R and 88482-E. I have a number of questions/clarifications. If you could get back to me as soon as possible it would be most helpful so that I can stay within the timelines. Questions are as follows:

88482-E:

1. page 3 of 7 of your data matrix: you have "all generic data" listed with the submitter as "any" and status is "pay". Page 4 of 7 goes on to list out the submitters names and addresses. We need you to send me (email is preferred) an updated data matrix listing out all of the generic data guideline by guideline with the submitter's name and status filled out for each. This is because the source is unregistered.

Please let me know when you can send this to me by so we can see if we can work with the current due date.

2. Just as an fyi, the product you cited as being similar has been transferred a few times since 2004. It is currently EPA reg# 71185-5. The most recent label though is from the original registration in 2004.

88482-R:

1. Can you clarify that this source is also unregistered? There was no EPA reg# filled out on the CSF so I'm assuming it's also unregistered. I'm also assuming that the unregistered source is not 88482-E, as the addresses are different. Can you please clarify?

2. If I'm wrong on #1 and it is a registered source, please provide me with a revised CSF filling out the reg # and disregard the following comments.

3. Assuming it's unregistered, I need updated data matrices for this product too. For the end-use product, we need a full data matrix. Currently the data matrix has the product chem and acute tox data listed on pages 1, 2 and 3 of 10. But we also need you to list out the generic data (guideline by guideline) for the end-use product since the assumption is that the source is not registered. Likewise, we need a data matrix for the source itself. This data matrix would also list out the product specific for the unregistered source as well as the generic data for the unregistered source. So you'd have two separate matrices. And again, you'd need to list the generic data guideline by guideline state the submitter's name for each guideline and the status.

I can not put the 88482-R product application into review with TRB until I have this information, so this one is on hold until I get this from you. If you can get it to us very soon, I doubt the due date would be affected. Otherwise, we may need to turn this one down and you can resubmit when you have the information. If I'm overlooking something in the package, please let me know as soon as possible.

Looking forward to hearing from you,
Heather

Need TRB to review for 88482-E

Heather A. Garvie
Registration Division

Office of Chemical Safety and Pollution Prevention (7504P)
U.S.EPA
1200 Pennsylvania Ave. NW
Washington, DC 20460
phone: 703-308-0034
www.epa.gov

Revised product chemistry report and CSF for oxytetracycline HCl

Matthew Brooks to: Shyam Mathur 07/07/2011 04:52 PM
Cc: Shaja Joyner

Matthew Brooks	Revised product chemistry report and CSF for oxytetracycline HCl	

Hi Shyam
As per our conversation today with Debbie McCall, attached find scans of revised CSF and product chemistry report for oxytetracline hcl technical.
I will submit 3 copies of the report to front end processing.
Thanks for all your help.
-Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

Revised version of MRID # 484857-01

Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com
(703) 266-4377 Fax

July 7, 2011

Document Processing Desk
Office of Pesticide Programs (7508C)
U.S Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington VA 22202

Attn: Shaja Joyner PM 20
Registration Division (RD)

Re: **Registration of Oxytetracycline Hydrochloride Technical**
EPA File Symbol

Dear Ms. Joyner:

On behalf of MGF Scientific Inc., Ag-Chem Consulting LLC is hereby submitting the following Product Chemistry data, formatted in accordance with Pesticide Registration notice 86-5, in support of registration of the above product.

Guideline	MRID	Study Title
OPPTS Series 830. (61, 62, 63, & 64)	**484851-01**	Oxytetracycline Hydrochloride, Product Chemistry, Group A : Product Identity, Composition and Analytical Test Guidelines and Group B: Physical and Chemical Properties Test Guidelines Study # TS001 **Revised July 7, 2011**

This report replaces the current submission for MRID#48485101 which was submitted on May 18, 2011.

Please feel free to contact me at 703-266-0128 if you have any questions concerning this submission.

Sincerely,

Matthew W. Brooks, Ph.D.
Ag-Chem Consulting LLC.
Authorized Representative of MGF Scientific Inc.

STUDY TITLE:	Oxytetracycline Hydrochloride, Product Chemistry, Group A: Product Identity, Composition and Analytical Test Guidelines and Group B: Physical and Chemical Properties Test Guidelines
DATA REQUIREMENT:	Pesticide Assessment Guidelines Subdivision C & D Section 158.150 – 158.190 Group A: Product Identity, Composition and Analytical Test Guidelines Group B: Physical and Chemical Properties Test Guidelines OPPTS Series 830 (61, 62, 63 & 64)
AUTHOR:	Dr. Matthew Brooks
STUDY COMPLETED ON: REVISED	April 29, 2011 July 7, 2011
SUBMITTER	Ag-Chem Consulting LLC 12208 Quinque Lane Clifton VA 20124
SPONSOR:	MGF Scientific Inc. P.O. Box 210847 Royal Palm Beach FL 33421
PROJECT ID	TS001

Pages 51-65 - *Access to FIFRA health and safety data is restricted under FIFRA section 10(g)*

STUDY TITLE:	Oxytetracycline Hydrochloride, Product Chemistry, Group A: Product Identity, Composition and Analytical Test Guidelines and Group B: Physical and Chemical Properties Test Guidelines
DATA REQUIREMENT:	Pesticide Assessment Guidelines Subdivision D Section 158.150 – 158.180 Group A: Product Identity, Composition and Analytical Test Guidelines OPPTS Series 830 (61, 62, & 64)
AUTHOR:	Matthew Brooks
STUDY COMPLETED ON: REVISED	April 29, 2011 July 7, 2011
SUBMITTER:	Ag-Chem Consulting, LLC 12208 Quinque Lane Clifton, VA 20124
SPONSOR:	MGF Scientific Inc. P.O. Box 210847 Royal Palm beach FL 33421
PROJECT ID	TS001

Confidential Attachment

Manufacturing process information may be entitled to confidential treatment

Pages 67-73 - *Access to FIFRA health and safety data is restricted under FIFRA section 10(g)*

Completion of 21-Day Content Screen

PM- 21

EPA Reg. #(File Symbol) 88482-E

Decision # D_____

Data package delivered to you on 5/25/11 .
(date)

Jacket/Mini-jacket will be transferred to you today.
(Pick up from Document Center) SH

Thank you,

Registration Division's 21–Day Content Team

88482-E

Memorandum

Date: 05/23/11

To: PM 21, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 20, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MATTHEW BROOKS
AG-CHEM CONSULTING
MGF SCIENTIFIC, INC.
12208 QUINQUE LANE
CLIFTON, VA 20124-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 18-MAY-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Re: Data Matrix follow-up
Matthew Brooks to: Shaja Joyner 07/07/2011 12:19 PM
Cc: Heather Garvie

Hi Shaja
Revised data matrix attached. Revised as requested in your email and as we discussed earlier today.
-Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

--- On Wed, 7/6/11, Shaja Joyner <Joyner.Shaja@epamail.epa.gov> wrote:

> From: Shaja Joyner <Joyner.Shaja@epamail.epa.gov>
> Subject: Re: Data Matrix follow-up
> To: "Matthew Brooks" <mwbrooks01@yahoo.com>
> Cc: "Heather Garvie" <Garvie.Heather@epamail.epa.gov>
> Date: Wednesday, July 6, 2011, 2:27 PM
>
> Thanks Matt. We're almost there. If the RED has
> waived a study, you do
> not have to list "Any" in the submitters column (please
> remove). Also
> on page 1, for the Primary Eye, Primary Dermal Irritation
> Rabbit, and
> Dermal sensitization you need to identify the submitter
> that you're
> paying.
>
> **********
> Shaja Brothers Joyner, Product Manager 20
> US EPA
> Office Chemical Safety and Pollution Prevention
> Registration Division/Fungicide Branch
> 1200 Pennsylvania Avenue, NW (7505P)
> Washington, DC 20460
>
> Tel:
> 703.308.3194 1 Fax:
> 703.605.0781
> E-Mail: joyner.shaja@epa.gov
> URL Address: www.epa.gov/pesticides
>
>
>
> From: Matthew Brooks <mwbrooks01@yahoo.com>
> To: Shaja Joyner/DC/USEPA/US@EPA
> Cc: Heather Garvie/DC/USEPA/US@EPA
> Date: 07/01/2011 11:30 AM
> Subject: Re: Data Matrix follow-up
>
>
>
> Revised Matrix attached.

Form Approved OMB No. 2070-0060

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date July 7, 2011	EPA Reg No./File Symbol 88482-E	Page 1 of 5
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.165	Description of formulation process	48485101	MGF Scientific Inc	OWN	
158.167	Discussion of impurities	48485101	MGF Scientific Inc	OWN	
157.175	Certified Limits	48485101	MGF Scientific Inc	OWN	
158.180	Enforcement Analytical Method	48485101	MGF Scientific Inc	OWN	
158.155	Product Identity and Composition	48485101	MGF Scientific Inc	OWN	
158.160	Description of Meterials used to formulate the product	48485101	MGF Scientific Inc	OWN	
158.162	Description of Formulation Process	48485101	MGF Scientific Inc	OWN	
870.1100	Acute Oral Tox- Rat			Waived	in RED
870.1200	Acute Dermal Tox-rat			Waived	in RED
870.1300	Acute Inhalation- Rat			Waived	in RED
870.2400	Primary Eye Irritation-Rabbit			Waived	in RED
870.2500	Primary Dermal Irritation- Rabbit			Waived	in RED
870.2600	Dermal Sensitization			Waived	In RED

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/7/11

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Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
				Waived	
				Waived	
				Waived	
				Waived	
				Waived	
				Waived	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/7/11

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DATA MATRIX

Date July 7, 2011	EPA Reg No./File Symbol 88482-E	Page 2 of 5
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308) Technical Product Matrix

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color	48485101	MGF Scientific Inc	OWN	
830.6303	Physical State	48485101	MGF Scientific Inc	OWN	
830.6304	Odor	48485101	MGF Scientific Inc	OWN	
830.6313	Stability to Normal and Elevated Temp., metals & metal io	48485101	MGF Scientific Inc	OWN	
830.6314	Oxidation/Reduction Chemical Incompatibility	48485101	MGF Scientific Inc	OWN	
830.6315	Flammability	48485101	MGF Scientific Inc	OWN	
830.6316	Explodability	48485101	MGF Scientific Inc	OWN	
830.6317	Storage Stability	48485101	MGF Scientific Inc	OWN	
.6319	Miscibility	48485101	MGF Scientific Inc	OWN	
830.6320	Corrosion Characteristics	48485101	MGF Scientific Inc	OWN	
830.6321	Dielectric Breakdown Voltage	48485101	MGF Scientific Inc	OWN	
830.7000	pH	48485101	MGF Scientific Inc	OWN	
830.7100	Viscosity	48485101	MGF Scientific Inc	OWN	
830.7200	Melting Point/Melting Range	48485101	MGF Scientific Inc	OWN	
830.7220	Boiling Point/Boiling Range	48485101	MGF Scientific Inc	OWN	

Signature	Name and Title	Date
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Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308) Technical Product Matrix

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
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			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
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			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
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Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	48485101	MGF Scientific Inc	OWN	
830.7370	Dissociation Constant In Water	48485101	MGF Scientific Inc	OWN	
830.7550, 830.7560 & 830.7570	Partition Coefficient	48485101	MGF Scientific Inc	OWN	
830.7840 & 830.7860	Water Solubility	48485101	MGF Scientific Inc	OWN	
830.7950	Vapor Pressure	48485101	MGF Scientific Inc	OWN	
830.1700	Preliminary Analysis	48485102	MGF Scientific Inc	OWN	
81A	90 Day Chronic Feeding- Rodent			Waived	In RED
82-B	90-Day Feeding- Nonrodent			Waived	In RED
82-2	21-Day Dermal- Rabbit/Rat			Waived	In RED
83-1 (a)	Chronic Feeding Toxicity- Rodent	00132394	Pfizer	Old	
83-1 (b)	Chronic Feeding Toxicity- nonRodents	00132395	Pfizer	Old	
83-2 (a)	Oncogenicity-Rat	00159856	U.S. Public Health	PL	
83-2 (b)	Oncogenicity- Mouse	00159856	U.S. Public Health	PL	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/7/11

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DATA MATRIX

Date July 7, 2011	EPA Reg No./File Symbol 88482-E	Page 3 of 5
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
				Waived	
				Waived	
				Waived	
			Pfizer	Old	
			Pfizer	Old	
			U.S. Public Health	PL	
			U.S. Public Health	PL	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/7/11

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Applicant's/Registrant's Name & Address IGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-3 (a)	Developmental Toxicity- Rat	00132391	Pfizer	Old	
83-3 (b)	Developmental Toxicity- Mouse	00132392	Pfizer	Old	
83-4	2-Generation Reproduction-Rat			Waived	in REO
71-1A	Acute Avian Oral- Quail/Duck	41777801	Pfizer	Old	
71-2A	Avian Dietary (LC50)-Quail	41777802	Pfizer	Old	
71-2B	Avian Dietary (LC50)- Duck	41777803	Pfizer	Old	
72-1A	Fish Acute (LC50)- Bluegill	41783201	Pfizer	Old	
72-1C	Fish Acute (LC50)- Trout	41783202	Pfizer	Old	
72-2A	Aquatic Invertebrate (EC50)	41783203	Pfizer	Old	
141-1	Honey Bee Acute Contact	41777804	Pfizer	Old	
161-1	Hydrolysis			Waived	in RED
161-2	Photodegradation- Water			Waived	in RED
161-3	Photodegradation- Soil			Waived	In RED
162-1	Aerobic Soil Metabolism			Waived	in RED
162-2	Anaerobic Soil Metabolism			Waived	In RED

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/7/11

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DATA MATRIX

Date July 7, 2011	EPA Reg No./File Symbol 88482-E	Page 4 of 5
Applicant's/Registrant's Name & Address GF Scientific inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Pfizer	Old	
			Pfizer	Old	
				Waived	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
				Waived	
				Waived	
				Waived	
				Waived	
				Waived	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/7/11

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DATA MATRIX

Date July 7, 2011	EPA Reg No./File Symbol 88482-E	Page 5 of 5
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12206 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006306)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]				Waived	
				Waived	
				Waived	
				Waived	
				Waived	
				Waived	
			EPA	PL	
			Geo Logic Corp	Pay	
			Geo Logic Corp	Pay	
			Geo Logic Corp	Pay	
			Geo Logic Corp	Pay	
			Geo Logic Corp	Pay	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/7/11

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DATA MATRIX

Date July 7, 2011	EPA Reg No./File Symbol 88482-E	Page 5 of 5
Applicant's/Registrant's Name & Address GF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
163-1	Leaching/Adsorp/Desorption			Waived	in RED
165-4	Bioaccumulation In Fish			Waived	In RED
84-2 (a)	Gene Mutation (Ames Test)			Waived	in RED
84-2 (b)	Structural Chromosomal Aberration			Waived	in RED
84-4	Other Genotoxic Effects			Waived	in RED
85-1	General Metabolism			Waived	in RED
	Antibiotic Resistance	40840101	EPA	PL	
835.2240	Aqueous Photolysis	47808901	Geo Logic Corp	Pay	
.2120	Hydrolysis	47808902	Geo Logic Corp	Pay	
835.4100	Aerobic Soil Metabolism	47808903	Geo Logic Corp	Pay	
835.6500	Terrestrial Field Participation	47808904	Geo Logic Corp	Pay	
835.1240	Adsorption/Desorption	47976202	Geo Logic Corp	Pay	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/7/11

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Re: Data Matrix follow-up
Shaja Joyner to: Matthew Brooks 07/06/2011 02:28 PM
Cc: Heather Garvie

Thanks Matt. We're almost there. If the RED has waived a study, you do not have to list "Any" in the submitters column (please remove). Also on page 1, for the Primary Eye, Primary Dermal Irritation Rabbit, and Dermal sensitization you need to identify the submitter that you're paying.

****

Shaja Brothers Joyner, Product Manager 20
US EPA
Office Chemical Safety and Pollution Prevention
Registration Division/Fungicide Branch
1200 Pennsylvania Avenue, NW (7505P)
Washington, DC 20460

Tel: 703.308.3194 I Fax: 703.605.0781
E-Mail: joyner.shaja@epa.gov
URL Address: www.epa.gov/pesticides

Matthew Brooks Revised Matrix attached. -Matt 07/01/2011 11:30:33 AM

From: Matthew Brooks <mwbrooks01@yahoo.com>
To: Shaja Joyner/DC/USEPA/US@EPA
Cc: Heather Garvie/DC/USEPA/US@EPA
Date: 07/01/2011 11:30 AM
Subject: Re: Data Matrix follow-up

Revised Matrix attached.
-Matt

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

--- On Fri, 7/1/11, Shaja Joyner <Joyner.Shaja@epamail.epa.gov> wrote:

> From: Shaja Joyner <Joyner.Shaja@epamail.epa.gov>
> Subject: Re: Data Matrix follow-up
> To: "Matthew Brooks" <mwbrooks01@yahoo.com>
> Cc: "Heather Garvie" <Garvie.Heather@epamail.epa.gov>
> Date: Friday, July 1, 2011, 9:42 AM
> Matt,
>
> I would encourage you to utilize EPA's Pesticide Submitters
> Data List instead of the RED to determine the companies
> that have developed data for oxytetracycline.
>
>
>
> ----- Original Message -----
> From: Matthew Brooks [mwbrooks01@yahoo.com]
> Sent: 06/30/2011 02:03 PM MST
> To: Shaja Joyner

> Cc: Heather Garvie
> Subject: Re: Data Matrix follow-up
>
>
>
> I will fill out what I can from the RED tomorrow and send
> it to you to look at. I've never had to find each and every
> study- in the past I've just had to list the guideline and
> then under submitter list any and under status list PAY.
>
> Matthew Brooks, Ph.D.
> 703-266-0128 Phone
> 703-266-4377 Fax
> mwbrooks01@yahoo.com
>
>
> --- On Thu, 6/30/11, Joyner.Shaja@epamail.epa.gov
> <Joyner.Shaja@epamail.epa.gov>
> wrote:
>
> > From: Joyner.Shaja@epamail.epa.gov
> <Joyner.Shaja@epamail.epa.gov>
> > Subject: Data Matrix follow-up
> > To: "Matthew Brooks" <mwbrooks01@yahoo.com>
> > Cc: Garvie.Heather@epamail.epa.gov
> > Date: Thursday, June 30, 2011, 2:36 PM
> >
> > Hi Matt,
> >
> > Thanks for the recent conference call clarifying the
> > pending
> > registration packages for oxytetracycline. As a
> > follow-up to the
> > matrices, I've attached the link of the form for
> > informational and
> > instructional purposes (see page 3). As previously
> > noted, the data
> > matrix form must be complete with all of the relevant
> > information:
> > guideline reference number, guideline study name,
> MRID#,
> > submitter, and
> > status. Please let us know if you are able to
> correct
> > within the next
> > week. As it stands, this package is subject to a 75
> > day deficiency
> > letter.
> >
> > Let's work together to address this issue in an effort
> to
> > avoid possible
> > delay of the Agency's review of this submission.
> >
> > Looking forward to hearing back from you.
> >
> > Regards,
> >
> **********
> > Shaja Brothers Joyner, Product Manager 20
> > US EPA

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DATA MATRIX

Date July 1, 2011	EPA Reg No./File Symbol 88482-E	Page 1 of 5
Applicant's/Registrant's Name & Address MGF Scientific inc. c/o Ag-Chem Consulting f2208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.165	Description of formulation process	48485101	MGF Scientific Inc	OWN	
158.167	Discussion of impurities	48485101	MGF Scientific Inc	OWN	
157.175	Certified Limits	48485101	MGF Scientific Inc	OWN	
158.180	Enforcement Analytical Method	48485101	MGF Scientific inc	OWN	
158.155	Product Identity and Composition	48485101	MGF Scientific Inc	OWN	
158.160	Description of Materials used to formulate the product	48485101	MGF Scientific Inc	OWN	
158.162	Description of Formulation Process	48485101	MGF Scientific Inc	OWN	
870.1100	Acute Oral Tox- Rat		Any	Waived	in RED
870.1200	Acute Dermal Tox-rat		Any	Waived	in RED
870.1300	Acute Inhalation- Rat		Any	Waived	In RED
870.2400	Primary Eye Irritation-Rabbit		Any	PAY	
870.2500	Primary Dermal Irritation- Rabbit		Any	PAY	
870.2600	Dermal Sensitization		Any	PAY	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/1/11

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Date July 1, 2011	EPA Reg No./File Symbol 88482-E	Page 1 of 5
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Cham Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			Any	Waived	
			Any	Waived	
			Any	Waived	
			Any	PAY	
			Any	PAY	
			Any	PAY	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/1/11

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Date July 1, 2011	EPA Reg No./File Symbol 88482-E	Page 2 of 5
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308) Technical Product Matrix

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color	48485101	MGF Scientific Inc	OWN	
830.6303	Physical State	48485101	MGF Scientific Inc	OWN	
830.6304	Odor	48485101	MGF Scientific Inc	OWN	
830.6313	Stability to Normal and Elevated Temp., metals & metal ions	48485101	MGF Scientific Inc	OWN	
830.6314	Oxidation/Reduction Chemical Incompatibility	48485101	MGF Scientific Inc	OWN	
830.6315	Flammability	48485101	MGF Scientific Inc	OWN	
830.6316	Explodability	48485101	MGF Scientific Inc	OWN	
830.6317	Storage Stability	48485101	MGF Scientific Inc	OWN	
830.6319	Miscibility	48485101	MGF Scientific Inc	OWN	
830.6320	Corrosion Characteristics	48485101	MGF Scientific Inc	OWN	
830.6321	Dielectric Breakdown Voltage	48485101	MGF Scientific Inc	OWN	
830.7000	pH	48485101	MGF Scientific Inc	OWN	
830.7100	Viscosity	48485101	MGF Scientific Inc	OWN	
830.7200	Melting Point/Melting Range	48485101	MGF Scientific Inc	OWN	
830.7220	Boiling Point/Boiling Range	48485101	MGF Scientific Inc	OWN	

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DATA MATRIX

Date July 1, 2011	EPA Reg No./File Symbol 88462-E	Page 2 of 5
Applicant's/Registrant's Name & Address GF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308) Technical Product Matrix

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Sciantific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	

Signature	Name and Title	Date
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DATA MATRIX

Date July 1, 2011	EPA Reg No./File Symbol 88482-E	Page 3 of 5
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	48485101	MGF Scientific Inc	OWN	
830.7370	Dissociation Constant In Water	48485101	MGF Scientific Inc	OWN	
830.7550, 830.7560 & 830.7570	Partition Coefficient	48485101	MGF Scientific Inc	OWN	
830.7840 & 830.7860	Water Solubility	48485101	MGF Scientific Inc	OWN	
830.7950	Vapor Pressure	48485101	MGF Scientific Inc	OWN	
830.1700	Preliminary Analysis	48485102	MGF Scientific Inc	OWN	
82-1A	90 Day Chronic Feeding- Rodent		Any	Waived	In RED
82-B	90-Day Feeding- Nonrodent		Any	Waived	in RED
82-2	21-Day Dermal- Rabbit/Rat		Any	Waived	in RED
83-1 (a)	Chronic Feeding Toxicity- Rodent	00132394	Pfizer	Old	
83-1 (b)	Chronic Feeding Toxicity- nonRodents	00 f32395	Pfizer	Old	
83-2 (a)	Oncogenicity-Rat	00 f59856	U.S. Public Health	PL	
83-2 (b)	Oncogenicity- Mouse	00159856	U.S. Public Health	PL	

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Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			MGF Scientific Inc	OWN	
			Any	Waived	
			Any	Waived	
			Any	Waived	
			Pfizer	Old	
			Pfizer	Old	
			U.S. Public Health	PL	
			U.S. Public Health	PL	

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Applicant's/Registrant's Name & Address IGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
83-3 (a)	Developmental Toxicity- Rat	00132391	Pfizer	Old	
83-3 (b)	Developmental Toxicity- Mouse	00132392	Pfizer	Old	
83-4	2-Generation Reproduction-Rat		Any	Waived	In RED
71-1A	Acute Avian Orat- Quail/Duck	41777801	Pfizer	Old	
71-2A	Avian Dietary (LC50)-Quait	41777802	Pfizer	Old	
71-2B	Avian Dietary (LC50)- Duck	41777803	Pfizer	Old	
72-1A	Fish Acute (LC50)- Bluegill	41783201	Pfizer	Old	
72-1C	Fish Acute (LC50)- Trout	41783202	Pfizer	Old	
72-2A	Aquatic Invertebrate (EC50)	41783203	Pfizer	Old	
141-1	Honey Bee Acute Contact	41777804	Pfizer	Old	
161-1	Hydrolysis		Any	Waived	in RED
161-2	Photodegradation- Water		Any	Weived	in RED
161-3	Photodegradation- Soil		Any	Waived	In RED
162-1	Aerobic Soil Metabolism		Any	Waived	in RED
162-2	Anaerobic Soil Metabolism		Any	Waived	in RED

Signature	Name and Title	Date
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Applicant's/Registrant's Name & Address IGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Pfizer	Old	
			Pfizer	Old	
			Any	Waived	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Pfizer	Old	
			Any	Waived	
			Any	Waived	
			Any	Waived	
			Any	Waived	
			Any	Waived	

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Applicant's/Registrant's Name & Address IGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
163-1	Leaching/Adsorp/Desorption		Any	Waived	In RED
165-4	Bioaccumulation In Fish		Any	Waived	In RED
84-2 (a)	Gene Mutation (Ames Test)		Any	Waived	In RED
84-2 (b)	Structural Chromosomal Aberration		Any	Waived	In RED
84-4	Other Genotoxic Effects		Any	Waived	In RED
85-1	General Metabolism		Any	Waived	In RED
	Antibiotic Resistance	40840101	EPA	PL	
835.2240	Aqueous Photolysis	47808901	Geo Logic Corp	Pay	
35.2120	Hydrolysis	47808902	Geo Logic Corp	Pay	
835.4100	Aerobic Soil Metabolism	47808903	Geo Logic Corp	Pay	
835.6500	Terrestrial Field Participation	47808904	Geo Logic Corp	Pay	
835.1240	Adsorption/Desorption	47976202	Geo Logic Corp	Pay	

Signature	Name and Title	Date
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Applicant's/Registrant's Name & Address IGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Any	Waived	
			Any	Waived	
			Any	Waived	
			Any	Waived	
			Any	Waived	
			Any	Waived	
			EPA	PL	
			Geo Logic Corp	Pay	
			Geo Logic Corp	Pay	
			Geo Logic Corp	Pay	
			Geo Logic Corp	Pay	
			Geo Logic Corp	Pay	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	7/1/11

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton VA 21024	
Active Ingredient(s) and/or representative test compound(s)	**Date**
Oxytetracycline HCl	May 17, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	**Product Name**
Terrestrial Nonfood and Ornamental	Oxytetracycline HCl Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	July 1, 2011	Matthew Brooks, Regulatory Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

oxytetracycline hydrochloride submissions - questions please!
Heather Garvie to: Matthew Brooks 06/22/201 t 02:05 PM

Hi Matthew:

I've been assigned to two oxytetracycline hydrochloride actions - 88482-R and 88482-E. I have a number of questions/clarifications. If you could get back to me as soon as possible it would be most helpful so that I can stay within the timelines. Questions are as follows:

88482-E:

1. page 3 of 7 of your data matrix: you have "all generic data" listed with the submitter as "any" and status is "pay". Page 4 of 7 goes on to list out the submitters names and addresses. We need you to send me (email is preferred) an updated data matrix listing out all of the generic data guideline by guideline with the submitter's name and status filled out for each. This is because the source is unregistered.

Please let me know when you can send this to me by so we can see if we can work with the current due date.

2. Just as an fyi, the product you cited as being similar has been transferred a few times since 2004. It is currently EPA reg# 71185-5. The most recent label though is from the original registration in 2004.

88482-R: — new pc / AT

1. Can you clarify that this source is also unregistered? There was no EPA reg# filled out on the CSF so I'm assuming it's also unregistered. I'm also assuming that the unregistered source is not 88482-E, as the addresses are different. Can you please clarify?

2. If I'm wrong on #1 and it is a registered source, please provide me with a revised CSF filling out the reg # and disregard the following comments.

3. Assuming it's unregistered, I need updated data matrices for this product too. For the end-use product, we need a full data matrix. Currently the data matrix has the product chem and acute tox data listed on pages 1, 2 and 3 of 10. But we also need you to list out the generic data (guideline by guideline) for the end-use product since the assumption is that the source is not registered. Likewise, we need a data matrix for the source itself. This data matrix would also list out the product specific for the unregistered source as well as the generic data for the unregistered source. So you'd have two separate matrices. And again, you'd need to list the generic data guideline by guideline state the submitter's name for each guideline and the status.

I can not put the 88482-R product application into review with TRB until I have this information, so this one is on hold until I get this from you. If you can get it to us very soon, I doubt the due date would be affected. Otherwise, we may need to turn this one down and you can resubmit when you have the information. If I'm overlooking something in the package, please let me know as soon as possible.

Looking forward to hearing from you,
Heather

Heather A. Garvie
Registration Division

21-Day Screen Completed by Contractor

21-Day Expires on 6-8-11

Jacket # 88482-E
MRID# 484851

Content Screen: Recommend to Pass/Fail

86-5 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHAIBLE

PM-21

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 5-18-11

Experts In-Processing Signature: MF Harrington Date 5-20-11 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes _____ Date _____

EPA Reg. Number: 88482-E	EPA Receipt Date: 5-18-11

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type	X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)	X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) Active inerts only — yes: X, no:			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)	X		
	Certificate and data matrix consistent	X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) — yes: , no:			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)	X		
	a) Selective Method (Fee category experts use) — yes: X, no:			
	b) Cite-All (Fee category experts use) — yes: , no:			
	c) Applicant owns all data (Fee category experts use) — yes: , no:			
6	**5 Copies of Label** (link to **http://www.epa.gov/oppfead1/labeling/lrm/**) **(Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)	X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

A few guidelines are listed in the studies as not required / applicable. Flammability, miscibility, dielectrics and viscosity. We leave it to the PM to decide how to proceed.

Initially the data matrix did not list any guidelines (and was unsigned) and the Certification with Respect to Citation of Data Form marked "cite all" despit the presence of data. The registrant was contacted and sent corrections 5/23/11.

No inerts for review – active + impurity only.

KM
5/23/11

Jacket passed.

Studies passed 86-5 review. MRID 484851

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even **if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Matthew Brookes
Phone #: (703) 266-0128
Email:

First Call/Initials:	**Second Call/Initials:**
Date:	**Date:**
Time:	**Time:**

This is Rachel Metz **, EPA contractor.**

I'm calling regarding your submission in support of Oxytetracycline HCl Technical (88482-E).

We have found the following deficiencies regarding:
PR Notice 86.5: Yes or (No)
Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: (Yes) or No

(Also, on end-use prod. Prel. Anal. isn't addressed in matrix)
IT'S IN THE STUDY
These deficiencies have been approved by EPA.
The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:
If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.

Oxytetracycline - new data matrix and citation form

Matthew Brooks to: Rachel Metz 05/23/2011 01:39 PM

Hi Rachel
See attached- let me know if these work.

With regard to the end use product ArborBiotic. It is formulated via a nonintegrated system; therefore Preliminary Analysis is not applicable for that product.

Sincerely
Matt Brooks

Matthew Brooks, Ph.D.
703-266-0128 Phone
703-266-4377 Fax
mwbrooks01@yahoo.com

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 19, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-449274
EPA File Symbol or Registration Number: 88482-E
Product Name: OXVTETRACYCLINE HCI TECHNICAL
EPA Receipt Date: 18-May-2011
EPA Company Number: 88482
Company Name: MGF SCIENTIFIC, INC.

MATTHEW BROOKS
AG-CHEM CONSULTING
MGF SCIENTIFIC, INC.
12208 QUINQUE LANE
CLIFTON, VA 20124-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{896195O~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 21

Receipt No. S-	896195
EPA File Symbol/Reg. No.	88482-E
Pin-Punch Date:	5/18/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R300

Granted: R300

Amount Due: $ 1,434.00

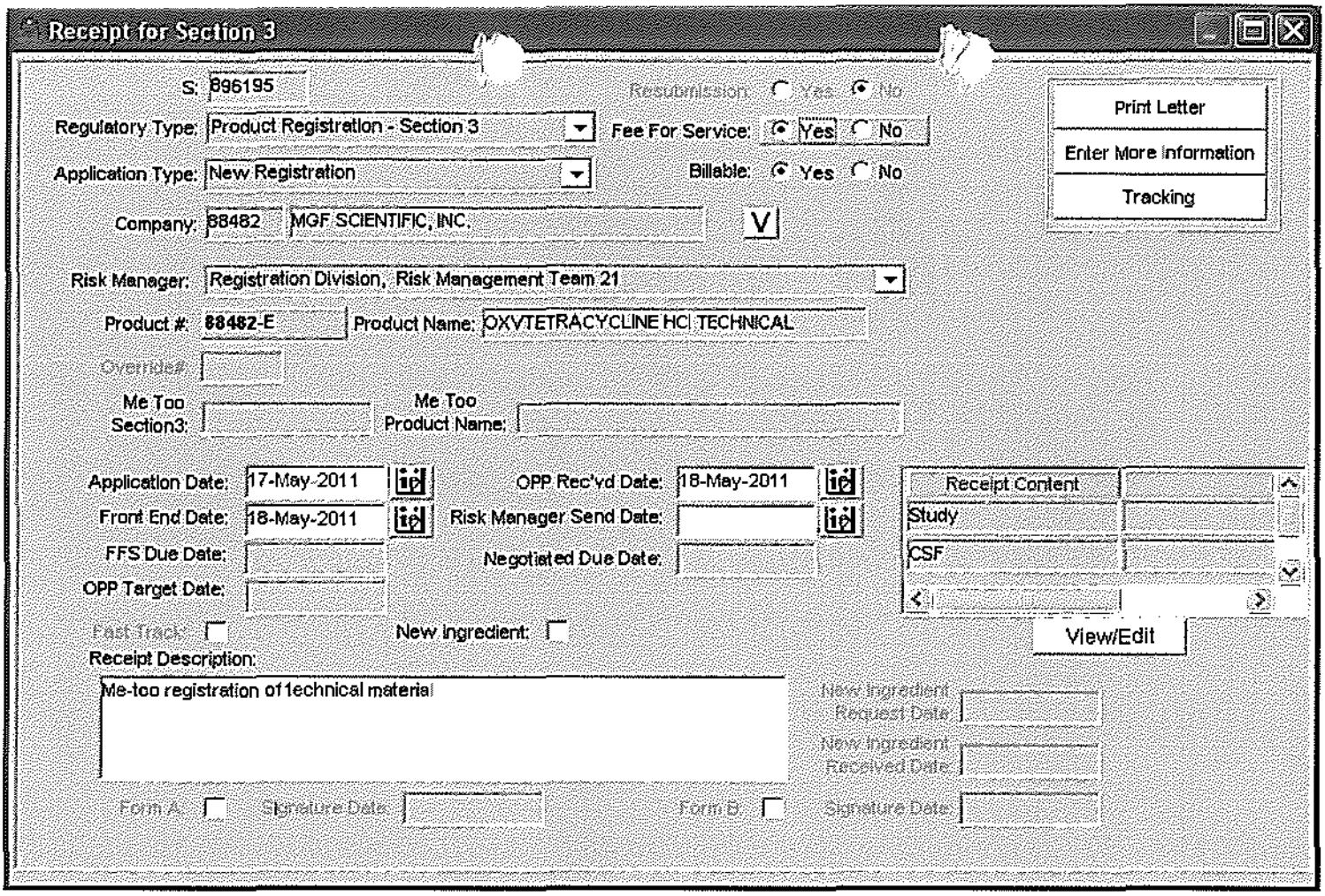
Parent/Child Decisions:

Active + impurity only inerts for review

☒ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: _____ Date: 5-15-11

Remarks:


Receipt for Section 3
S: 896195
Resubmission: Yes No
Print Letter
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Enter More Information
Application Type: New Registration
Billable: Yes No
Tracking
Company: 88482 MGF SCIENTIFIC, INC.
Risk Manager: Registration Division, Risk Management Team 21
Product #: 88482-E
Product Name: OXYTETRACYCLINE HCl TECHNICAL
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 17-May-2011
OPP Rec'vd Date: 18-May-2011
Front End Date: 18-May-2011
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Me-too registration of1echnical materia
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Online Payment

Step 3: Confirm Payment 1 | 2 | 3

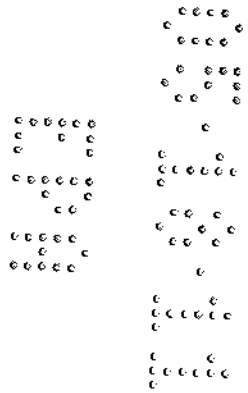
Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 253COLPV
Agency Tracking ID: 74202240832
Transaction Date and Time: 05/17/2011 20:06 EDT

Payment Summary

Address Information		Account Information		Payment Information	
Account Holder Name:	Matthew Brooks	**Card Type:**	Visa	**Payment Amount:**	$1,434.00
Billing Address:	12208 Quinque Lane	**Card Number:**	**********1584	**Transaction Date and Time:**	05/17/2011 20:06 EDT
Billing Address 2:		**Decision Number:**			
City:	Clifton	**Registration Number:**			
State / Province:	VA	**Company Name:**	MGF Scientific Inc.		
Zip / Postal Code:	20124	**Company Number:**			
Country:	USA	**Action Code:**	R300		



Ag-Chem Consulting
Pesticide Science and Registration
12208 Quinque Lane, Clifton VA 20124
(703) 266-0128 mwbrooks01@yahoo.com

May 17, 2011

Ms. Mary Watler
PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)
Office of Pesticide Programs
Document Processing Desk
Office of Pesticide Programs (7508C)
One Potomac Yard
2777 S. Crystal Dr.
Arlington VA 22202

Subject: Me-Too **Application for Oxytetracycline Hydrochloride Technical**

Dear Ms. Waller:
Ag- Chem Consulting, on behalf of MGF Scientific Inc, hereby submits the following new product registration. Oxytetracycline Hydrochloride is an antibiotic registered for control of bacteria and fungi infections in trees and also for use as an antifoulant. Uses for this technical product are limited to terrestrial nonfood and domestic outdoor. We are not supporting uses as an antifoulant or in edible food bearing trees although registrants may use this product for those uses provided they cite all applicable data.

In support of this registration we have submitted:
A completed application;
A completed data matrix
A certification with respect to data citation. We have chosen the cite-all method of support for this product.
A letter of Authorization for Ag-chem consulting to act on behalf of MGK Scientific Inc.
Five Copies of the proposed label.
Appropriate product chemistry

We believe this application should be PRIA coded R300, Substantially similar product, cite-all support, product chemistry only. We have enclosed a receipt for 1, 434.00

We have under separate cover submitted an application for an end use product composed of this technical.

If you have additional questions please do not hesitate to contact me at 703-266-0128.
Sincerely,

Matthew Brooks
An Authorized Representative of MGF Scientific Inc.

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	✓	
870.1200	Acute Dermal (LD50)	✓	
870.1300	Acute Inhalation (LC50)	✓	
870.2400	Acute Eye Irritation	✓	
870.2500	Acute Dermal Irritation	✓	
870.2600	Dermal Sensitization	✓	

Efficacy – which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants		✓	
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments		✓	
810.3300	Treatments to Control Pests of Humans and Pets		✓	✓
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments		✓	✓
810.3500	Premises Treatments		✓	✓
810.3600	Structural Treatments		✓	
810.3800	Methods for Efficacy Testing of Termite Baits		✓	

R 300 and 301

100% identical (repack): YES or NO (circle one)
{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group and A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	X	
830.1600	Description of materials used to produce the product	X	
830.1650	Description of formulation process	X	
830.1670	Discussion on the formation of impurities	X	
830.1700	Preliminary analysis	X	
830.1750	Certified limits (158.345)	X	
830.1800	Enforcement analytical method	X	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted		
		Yes	No	
830.6302	Color	X		
830.6303	Physical State	X		
830.6304	Odor	X		
830.6314	Oxidation/Reduction (Chemical incompatibility)	X		
830.6315	Flammability		X	not req.
830.6316	Explodability	X		
830.6317	Storage stability	X		
830.6319	Miscibility		X	NA
830.6320	Corrosion Characteristics	X		
830.6321	Dielectric Breakdown voltage		X	NA
830.7000	pH	X		
830.7100	Viscosity		X	NA
830.7300	Density	X		

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060, Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

☑ Registration ☐ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: MGF Scientific Inc. / 88482-E

2. EPA Product Manager: Waller

3. Proposed Classification: ☑ None ☐ Restricted

4. Company/Product (Name): MGF Scientific Inc. / Oxytetracycline HCl Tech

PM#: 21

5. Name and Address of Applicant (Include ZIP Code)

MGF Scientific Inc. c/o Ag-Chem Consulting
12208 Quinque Lane
Clifton VA 20124

☑ Check if this is a new address

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 74896-5
Product Name RG OTC Technical

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☑ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional pagets) if necessary. (For section I and Section II.)

Me-Too Registration of technical material. Cite-all method of support. Proposed PRIA Code R300.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☑ Label ☐ Container

4. Size(s) Retail Container: 55 lbs.

5. Location of Label Directions: ☑ On Container Label

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Matthew Brooks	Regulatory Consultant	703-266-0128

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature

3. Title: Regulatory Consultant

4. Typed Name: Matthew Brooks

5. Date: 5/17/2011

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number MGF Scientific Inc. c/o Ag-Chem Consulting 12206 Quinque Lane Clifton VA 21024	EPA Registration Number/File Symbol
Active Ingredient(s) and/or representative test compound(s) Oxytetracycline HCl	Date May 17, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Nonfood and Ornamental	Product Name Oxytetracycline HCl Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	5-17-2011	Matthew Brooks, Regulatory Agent

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DATA MATRIX

Date May 17, 2011	EPA Reg No./File Symbol	Page 1 of 7
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.165	Description of formulation process		MGF Scientific Inc	Submitted	
158.167	Discussion of impurities		MGF Scientific Inc	Submitted	
157.175	Certified Limits		MGF Scientific Inc	Submitted	
158.180	Enforcement Analytical Method		MGF Scientific Inc	Submitted	
158.155	Product Identity and Composition		MGF Scientific Inc	Submitted	
158.160	Description of Materials used to formulate the product		MGF Scientific Inc	Submitted	
158.162	Description of Formulation Process		MGF Scientific Inc	Submitted	
870.1100	Acute Oral Tox- Rat		Any	PAY	
870.1200	Acute Dermal Tox-rat		Any	PAY	
870.1300	Acute Inhalation- Rat		Any	PAY	
870.2400	Primary Eye Irritation-Rabbit		Any	PAY	
870.2500	Primary Dermal Irritation- Rabbit		Any	PAY	
870.2600	Dermal Sensitization		Any	PAY	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	5/17/11

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DATA MATRIX

Date May 17, 201 t	EPA Reg No./File Symbol	Page 2 of 7
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308) Technical Product Matrix

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6302	Color		MGF Scientific Inc	Submitted	
830.6303	Physical State		MGF Scientific Inc	Submitted	
830.6304	Odor		MGF Scientific Inc	Submitted	
830.6313	Stability to Normal and Elevated Temp., metals & metal i		MGF Scientific Inc	Submitted	
830.6314	Oxidation/Raduction Chemical Incompatibility		MGF Scientific Inc	Submitted	
830.63 f5	Flammability		MGF Scientific Inc	Submitted	
830.6316	Explodability		MGF Scientific Inc	Submitted	
830.6317	Storage Stability		MGF Scientific Inc	Submitted	
830.6319	Miscibility		MGF Scientific Inc	Submitted	
830.6320	Corrosion Characteristics		MGF Scientific Inc	Submitted	
830.632 f	Dielectric Breakdown Voltage		MGF Scientific Inc	Submitted	
830.7000	pH		MGF Scientific Inc	Submitted	
830.7100	Viscosity		MGF Scientific Inc	Submitted	
830.7200	Melting Point/Melting Range		MGF Scientific Inc	Submitted	
830.7220	Boiling Point/Boiling Range		MGF Scientific Inc	Submitted	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	5/17/11

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Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density		MGF Scientific Inc	Submitted	
830.7370	Dissociation Constant In Water		MGF Scientific Inc	Submitted	
830.7550, 830.7560 & 830.7570	Partition Coefficient		MGF Scientific Inc	Submitted	
830.7840 & 830.7860	Water Solubility		MGF Scientific Inc	Submitted	
830.7950	Vapor Pressure		MGF Scientific Inc	Submitted	
830.1700	Preliminery Analysis		MGF Scientific Inc	Submitted	
	All Generic Deta		Any	Pay	

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	5/17/11

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Date May 17, 2011	EPA Reg No./File Symbol	Page 4 of 7
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Crop Protection, LLC		
			P.O. Box 18300		
			Greensboro, NC 27419		
			Pfizer Inc		
			7000 Portage road, KZO 300-403 SW		
			Kalamazoo, MI 49001		
			J. J. Mauget CO.		
			12733 Director's Loop		
			Woodbridge, VA 22192		
			Spray Drift Task Force		
			1900 K Street, NW		
			Washington, DC 20005		

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	5/17/11

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DATA MATRIX

Date May 17, 2011	EPA Reg No./File Symbol	Page 5 of 7
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technicat	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Quimica Agronomica de Mexico, S. DE R.		
			370 South Main Street		
			Yuma, Az 85364		
			GEO Logic Corp		
			P.O. Box 1341		
			Mountainside, NJ 07092		
			Outdoor Residential Exposure Task Force		
			1350 I Street, N.W.		
			Washington, DC 20005		
			Agricultural Reentry Task Force		
			1350 I Street, N.W.		
			Washington, DC 20005		

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	5/17/11

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DATA MATRIX

Date May 17, 2011	EPA Reg No./File Symbol	Page 6 of 7
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20f24	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Rainbow Treecare Scientific Advancement		
			t1571 K-Tel Drive		
			Minnetonka, MN 55343		
			Regguide		
			509 Tower Valley Drive		
			Hillsboro, MO 63050		
			Agricultural Handlers Exposure Task Force		
			P.O. Box 509		
			1720 Prospect Drive		
			Macon, MO 63552		

Signature	Name end Title Matthew Brooks Regulatory Consultant	Date 5/17/11

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Date May 17, 2011	EPA Reg No./File Symbol	Page 7 of 7
Applicant's/Registrant's Name & Address MGF Scientific Inc. c/o Ag-Chem Consulting 12208 Quinque Lane Clifton Va 20124	Product Oxytetracycline HCl Technical	

Ingredient Oxytetracycline HCl (P C code 006308)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Agrosource, Inc		
			P.O. Box 1341		
			Mountainside, NJ 07092		
			Generic Endangered Species Task Force		
			4110 136th Street, Northwest		
			GIG Herbor, WA 98332		

Signature	Name and Title	Date
	Matthew Brooks Regulatory Consultant	5/17/11

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Oxytetracycline Hydrochloride Technical

This material is a technical antibiotic product intended for formulation into EPA-registered end-use pesticide products.

Not for use or consumption by humans or animals.

Not for Resale under this Label.

Active Ingredient:	
Oxytetracycline hydrochloride*	99.0%
Other Ingredients:	1.0%
	100.00%

*Equivalent to 91.7% oxytetracycline

Net Contents:

EPA Reg. No. **EPA Est No.**

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID **Call a poison control center or doctor immediately for treatment advice.**	
If in Eyes:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
If On Skin or Clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact the American Association of Poison Control Centers at 1-800-222-1222 for emergency medical treatment information.	

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened and undamaged, and the purchase price will be refunded.

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield or safety glasses). May cause allergic skin reactions. Do not breathe dust. Wear dust mask and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. This material is not to be used for medical, veterinary, or human purposes.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This manufacturing use product is intended to be formulated as an active ingredient into end-use pesticide products. The manufacturer of such products shall be responsible for registering its products with the EPA as a pesticide for acceptable use patterns.

Only for formulation into an antibacterial pesticide for the following uses:
Terrestrial Non-Food & Domestic Outdoor

This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U. S. EPA data submission requirements regarding the support of such uses.

Storage & Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Keep container tightly closed and sealed. Product is moisture, temperature and light sensitive. Product is hygroscopic so protect from moisture. Store in a cool (77°F, 25°C), dry place away from heat and open flames with minimum exposure to the atmosphere. Avoid extremes in temperature.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

Container Disposal: Non-refillable container. Do not reuse or refill this container. Then offer for recycling if available or dispose of the empty container in a sanitary landfill or by incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Conditions of Sale and Limitation of Warranty and Liability

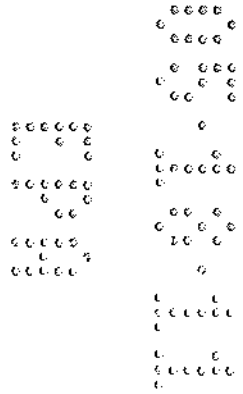
The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, materials, resistant strains or other influencing factors in the use of the products, which are beyond the control of MGF Scientific, Inc. or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold MGF Scientific, Inc. and Seller harmless for any claims relating to such factors.

MGF Scientific, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with direction under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or MGF Scientific, Inc. and Buyer and User assume the risk of any such use. MGF SCIENTIFIC, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall MGF Scientific, Inc. or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MGF SCIENTIFIC, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OR WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF MGF SCIENTIFIC, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.

MGF Scientific, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of MGF Scientific, Inc.

MGF Scientific, Inc.
P.O. Box 210847
Royal Palm Beach, FL 33421
(561) 798-1377



MGF Scientific, Inc.
P.O. Box 210847
Royal Palm Beach, FL 33421
561-798-1377

To: Office of Pesticide Programs (7508C)
U. S. EPA
One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

To Whom It May Concern,

Please note that Dr. Matthew Brooks and Ag-Chem Consulting are authorized to act on behalf of MGF Scientific, Inc. for all Federal EPA and State Pesticide registration and regulatory matters.

Sincerely,

Richard Maxwell
President

NEW APPLICATIONS

DATE: MAY 18 2011

FILE NUMBER: 88482-E

FEP (OPPIN ENTRY) LV MAY 18 2011
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

✓ **ASSIGN TO PM** 21 **(NO DATA)**

____ **JACKET TO SHELF (DATA)**

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